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SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/346,910	11/30/94	LIPTON	S 00108017004

EXAMINER	
GUCKER, S	

18N2/1102

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ART UNIT	PAPER NUMBER
1812	6

DATE MAILED: 11/02/95

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☑ This application has been examined ☐ Responsive to communication filed on _____ ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), ___ days from the date of this letter. Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☐ Notice of References Cited by Examiner, PTO-892.
2. ☐ Notice of Draftsman's Patent Drawing Review, PTO-948.
3. ☑ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Patent Application, PTO-152.
5. ☐ Information on How to Effect Drawing Changes, PTO-1474.
6. ☐ _____.

Part II SUMMARY OF ACTION

1. ☑ Claims 1-7 are pending in the application.
   Of the above, claims 2-7 are withdrawn from consideration.
2. ☐ Claims _____ have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☑ Claims 1 are rejected.
5. ☐ Claims _____ are objected to.
6. ☑ Claims 1-7 are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____. has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).
12. ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____.
13. ☐ Since this application apppears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

Part III DETAILED ACTION

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I. Claim 1, drawn to nucleic acid, classified in Class 536, subclass 23.5.

Group II. Claims 2-6, drawn to a polypeptide, classified in Class 530, subclass 350.

Group III. Claim 7, drawn to a method of promoting regeneration, classified in Class 514, subclass 2.

The inventions are distinct, each from the other because of the following reasons:

Groups II and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the protein of Group II can be used to make antibodies for detection or isolation of antigenically similar proteins.

Group I is directed to a product that is not used in or produced by the method of Group III, and is not required one for the other.

Although there are no provisions under the section for "Relationship of Inventions" in MPEP 806.05 for "inventive groups that are directed to different products; restriction is deemed to be proper because these products appear to constitute patentably distinct inventions for the following reasons:

Groups I and II are directed to products that are distinct both physically and functionally, and are therefore patentably distinct, and are not required one for the other. Further, the nucleic acid of Group I can be used other than to make the polypeptide of Group II, such as its use in gene therapy. The polypeptide of Group II can be obtained other than by using the nucleic acid of Group I to make it, such as its isolation and purification from natural sources.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, as shown by their different classification, and because the search and examination of these groups are different, restriction for examination purposes as indicated is proper because the search and examination of these groups is different and would pose an undue burden to the examiner.

During a telephone conversation with John Freeman made on 9/22/95 a provisional election was made with traverse to prosecute the invention of Group I. Affirmation of this election

must be made by applicant in responding to this Office action. Claims 2-7 are withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b), as being drawn to a non-elected invention.

2. The oath or declaration is defective. A new oath or declaration in compliance with 37 C.F.R. § 1.67(a) identifying this application by its Serial Number and filing date is required. See M.P.E.P. §§ 602.01 and 602.02.

The oath or declaration is defective because:
Non-initialed alterations have been made to the oath or declaration (see 37 C.F.R. §§ 1.52(c) and 1.57).

The Applicant's residence and Post Office address' have been altered.

3. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to adequately describe and teach how to make and/or use the invention, i.e. failing to provide an enabling disclosure.

The specification does not describe any of the members of the Markush group in sufficient detail to enable the skilled

artisan to make or use the invention. The reasons for this are set forth below.

First, 68075_{DNA} is a 500 bp sequence (page 8, lines 26-28) that the skilled artisan could not make because the sequence is not disclosed. The only way to screen for the presence of this sequence as disclosed in the specification is through the use of anti-idiotypic antibodies TEPC-15 and HOPC-8 (page 8, line 25). Applicant's belief that the antibodies are available from Pillemer *et al.* or Sigma (St. Louis) or Hazelton Labs (PA) does not meet the burden of demonstrating that they were readily available to one of ordinary skill in the art. In view of this, the deposit of the hybridomas that produce these antibodies would be required under the deposit rules. See MPEP 2402-2411.05. In the absence of any sequence information or the availability of the hybridomas that produce the antibodies that can detect the sequence's product (in subcloning procedures using ATCC Deposit No.68075, for example), the skilled artisan would be unable to make the claimed invention. Even if ATCC Deposit No.68075 was obtained by the skilled artisan, which contains the 500 bp sequence, the specification does not describe the vector or cell that the 500 bp sequence is present in. One would be required to sequence the whole vector and then determine which 500 bp sequence would be the novel insert. The skilled artisan would not be able to make the claimed inventions because no information

is disclosed concerning the vectors that the two clones, 68075_{DNA} and TR2B, are contained in in the cells identified as ATCC Deposit No. 68075 and 75949, respectively. Without this information, clones 68075_{DNA} and TR2B cannot be used by the skilled artisan because he would not know which restriction sites the vectors contain, which restriction enzymes to use to excise the vectors from the host cells' DNA, what promoter regions the vectors contain and what conditions are appropriate to express the encoded polypeptide, etc. Thus, these clones are not adequately described nor are they enabled.

Second, even if the skilled artisan could recreate or determine the 500 bp clone, he cannot rescreen to reproduce or identify the other claimed clones TR2A, TR2B, TR3A, TR3B, and TR3C (page 8, lines 29-33) because insufficient conditions are disclosed in the specification as to what was performed. No sequence information is provided for these other clones and the skilled artisan could not make the sequences that comprise these clones based on the disclosure.

It is noted that clones TR2A, TR3A, TR3B, and TR3C have not been deposited and the only information provided on these clones is found on page 8, lines 29-33, which describes that TR2A is two kilobases and the other clones are three kilobases. No other information on these clones is provided in the disclosure.

Third, a nucleic acid sequence that hybridizes with any of the above clones under stringent conditions is not enabled because a virtually limitless number of possible sequences, varying in length from 15-20 bp up to sequences that are even larger than the thousands of nucleotides that comprise the larger clones in the claim have received no support in the specification in terms of examples or guidance. Indeed, the specification is silent on providing even one example of a sequence or rules of guidance for a nucleic acid sequence that hybridizes to the claimed invention under low stringency conditions. Without sufficient examples or guidance, the synthesis and testing of a virtually limitless number of possible sequences to determine their suitability for hybridizing under any conditions, let alone high stringency conditions, would constitute undue experimentation. In essence, then, the specification does not provide any criteria that the skilled artisan could use, nor any working examples from which one could extrapolate, the extent of hybridization of any nucleic acid sequence under any conditions that would be predictable with respect to any assurance that any particular sequence constructed by the skilled artisan would hybridize with sufficient specificity so as to enable the use of such a sequence in any way set forth in the specification (as a probe, to make protein, etc.).

It is noted that the use of the terms "low" or "high" to modify stringency of hybridization conditions is vague and relative to the specific physical conditions under which the hybridization is performed, and will also depend on the specific nucleotide sequences of the nucleic acids undergoing hybridization.

4. No claim is allowed.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen Gucker whose telephone number is (703) 608-6571. The examiner can normally be reached on Monday to Friday from 0800 to 1630.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Garnette Draper, can be reached on (703) 308-4232. The fax phone number for this Group is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

SG

Stephen Gucker

October 26, 1995

Marianne P. Allen

MARIANNE P. ALLEN
PRIMARY EXAMINER
GROUP 1800